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Filed : February 11, 2004

REMARKS

Claims 31, 32, 34-50 and 99-102 are pending in the present application. Claims 31, 49, and 99 have been amended. New Claims 124 and 125 have been added. The claims set forth above include markings to show the changes made by way of the present amendment, deletions being in ~~strikeout~~ or [[double brackets]] and additions being underlined.

In response to the Office Action mailed March 12, 2009, Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments.

The Proposed Combination of Johnson/Smith Does Not Make Amended Claim 31 Obvious

Independent Claim 31 stands rejected under 35 U.S.C. § 103(a) as being obvious under Johnson *et al.* (U.S. Patent No. 6,311,838) (“Johnson”) in view of Smith *et al.* (U.S. Patent No. 6,402,724) (“Smith”). Applicant respectfully traverses the present rejection. However, to expedite the prosecution of the present application, Applicant has amended Claim 31. Applicant submits that no new matter has been added and that the amendments are supported in the specification. *See, e.g.*, paragraph [0228]. Applicant also expressly reserves the right to further prosecute the original versions of Claim 31 and any claims dependent on it through continuation practice.

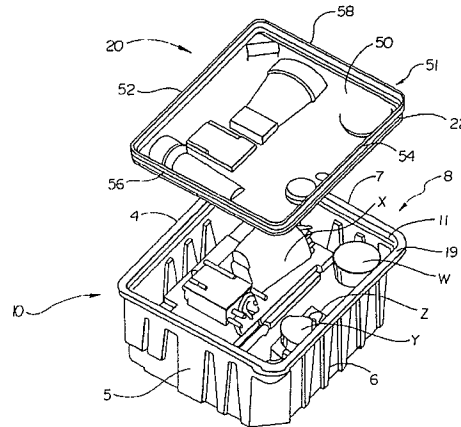
Amended Claim 31 recites an irrigation kit comprising:

a flexible sheet having an aperture configured to engage an irrigation device;
a basin for collecting irrigation fluid used during an irrigation procedure, the basin being sterilized and made of a biocompatible hypoallergenic material;
wherein the aperture, in an enlarged state, **is configured to fit over a conical splash shield** extending distally from a collar attached to a tip of the irrigation device;
wherein the flexible sheet is sized to cover a wound area and the basin; and
a cover providing a seal over the kit so as to keep the flexible sheet and basin in a sterilized state.

(Emphasis Added)

On page 3 of the Office Action, the Examiner asserts that Johnson teaches the claimed kit except for the flexible sheet and that Smith teaches “a wound irrigation shield that includes a flexible sheet with an adjustable aperture as set forth in the abstract.”

Johnson discloses an integrated packaging system for packaging medical components. See Figure 1 from Johnson, reproduced below.



Not only does Johnson not teach a flexible sheet as the Examiner notes, Johnson also does not teach a basin for collecting irrigation fluid used during an irrigation procedure. Persons skilled in the art would not consider the packaging container 10 as a basin for collecting irrigation fluid during an irrigation procedure.

Smith teaches a splash shield for use in wound irrigation. The splash shield is made of flexible material “to adapt to the fluid end portion of any number and variety of irrigation fluid delivery devices.” Smith, Abstract. See also Figures 1 and 2 from Smith reproduced below.

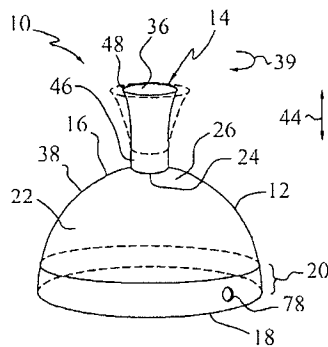


FIG. 1

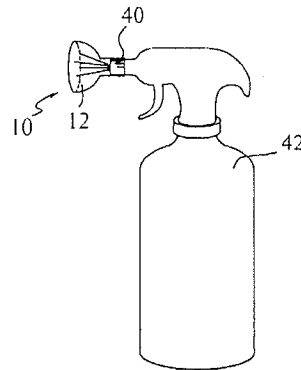


FIG. 2

Claim 31 recites a flexible sheet having an aperture configured to fit over a conical splash shield. The flexible sheet and the conical splash shield are not the same device.

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In contrast, the Examiner seems to be asserting that the Smith shield can be configured to fit over another splash shield. However, Smith does not teach this. Smith teaches that his splash shield can be “adaptable to a variety of fluid delivery devices used for delivering an irrigation fluid to a wound site.” Smith, Col. 3, ll. 13-15. The Smith shield is the splash shield to be configured on a fluid deliver device, not another splash shield. In addition, persons skilled in the art would not place one splash shield over another splash shield.

This distinction between the flexible sheet and a splash shield is important. Especially in the area of orthopedic surgery, large amounts of irrigation fluid are used. In addition, tissue, bone fragments, and other contaminants pose a risk to the practitioner. *See, e.g.*, paragraphs [0009]-[0011]. Prior art splash shields do not provide adequate protection for the practitioner. *See, e.g.*, Figure 2 of Robinson shown above. The flexible sheet as described in certain embodiments of the present application provides more surface area for protection.

As amended Claim 31 further recites, “the flexible sheet is sized to cover a wound area and *the basin*.” The flexible sheet is preferably four feet in length, and can be sized, *e.g.*, shortened, depending on the irrigation procedure. *See, e.g.*, paragraph [0224].

In contrast, Smith does not teach a flexible sheet sized to cover a wound area and *the basin*. The Examiner notes that “Smith discloses a flexible sheet that has a length as set forth in the figures.” Office Action, page 8 (for rejection of another claim in view of Smith). As seen in Figure 2 of Smith, reproduced above, the Smith shield is not sized to cover a wound area and a basin. In addition, the Smith shield cannot be varied once it is manufactured.

The Examiner asserts that “[i]t would have been obvious to one of ordinary skill in the art to modify the length of Smith in order to determine the most effective product...” Office Action, page 8. M.P.E.P. § 2144.04 cites *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), where the Federal Circuit held that “where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.”

Here, however, the claimed device is patentably distinct from the prior art because a flexible sheet sized to cover a wound and a basin would perform differently than the Smith shield. As mentioned above, the flexible sheet of Claim 31 provides adequate protection for the

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practitioner from the large amounts of fluid, tissue, bone fragments, and contaminants typical from orthopedic surgery. The Smith shield, *see, e.g.*, Robinson Figures above, could not perform in this way. In addition, persons skilled in the art would not modify the Smith shield to the relative size as recited in amended Claim 31 because prior art splash shields are not within this working range.

For at least the forgoing reasons, Applicant submits that the combination of Johnson and Smith does not render Claim 31 obvious. Therefore, Applicant requests that the Examiner withdraw the rejection of Claim 31 and pass Claim 31 to allowance.

The Proposed Combination of Holloway/Smith Does Not Make Amended Claim 49 Obvious

Independent Claim 49 stands rejected under 35 U.S.C. § 103(a) as being obvious under Holloway *et al.* (U.S. Patent No. 5,381,562) (“Holloway”) in view of Smith. Applicant respectfully traverses the present rejection. However, to expedite the prosecution of the present application, Applicant has amended Claim 49. Applicant submits that no new matter has been added and that the amendments are supported in the specification. *See, e.g.*, paragraph [0228]. Applicant also expressly reserves the right to further prosecute the original versions of Claim 49 and any claims dependent on it through continuation practice.

Claim 49 recites an irrigation kit comprising:

- a flexible sheet having an aperture configured to engage an irrigation device comprising a conical splash shield extending distally from a collar attached to a tip of the irrigation device, material of the **flexible sheet being configured** and sized to, in an enlarged state, **to fit over the conical splash shield**;
- and

- a basin for collecting irrigation fluid used during an irrigation procedure, the basin being sterilized and made of a biocompatible hypoallergenic material;

- wherein the basin has at least one surface, said surface having at least one convertible portion configured to be convertible between a complete leak proof wall and an aperture configured to allow the basin to be drained through the aperture;

- wherein **the flexible sheet is sized to cover a wound area and the basin.**

(Emphasis Added)

Holloway discloses a contoured basin. Smith is discussed above. On page 6 of the Office Action, the Examiner uses Smith as teaching “a wound irrigation shield that includes a flexible sheet.” For at least the same reasons discussed above with respect to Claim 31, Smith does not teach either a flexible sheet being configured to fit over a conical splash shield or a

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flexible sheet sized to cover a wound area and a basin. Holloway, which teaches a basin, does not rectify these failures.

For at least the forgoing reasons, Applicant submits that the combination of Holloway and Smith does not render Claim 49 obvious. Therefore, Applicant requests that the Examiner withdraw the rejection of Claim 49 and pass Claim 49 to allowance.

The Proposed Combination of Marogil/Smith Does Not Make Amended Claim 99 Obvious

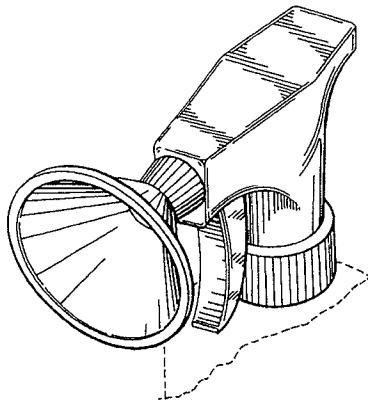
Independent Claim 99 stands rejected under 35 U.S.C. § 103(a) as being obvious under Marogil (Des 386,684) (“Marogil”) in view of Smith. Applicant respectfully traverses the present rejection. However, to expedite the prosecution of the present application, Applicant has amended Claim 99. Applicant submits that no new matter has been added and that the amendments are supported in the specification. *See, e.g.*, paragraph [0228]. Applicant also expressly reserves the right to further prosecute the original versions of Claim 99 and any claims dependent on it through continuation practice.

Amended Claim 99 recites an irrigation shield comprising:

a flexible sheet having an elastically enlargeable aperture configured to fit over and releasably engage a head of an irrigation device comprising **a flexible splash shield** having proximal collar and a conical body that diverges in a distal direction away from the collar toward a distal rim; wherein **the flexible sheet is sized to cover a wound area and an irrigation basin.**

(Emphasis Added)

Marogil teaches an ornamental design for an antiseptic spray nozzle and guard. See Figure 1 of Margil reproduced below. Smith is discussed above.



On page 8 of the Office Action, the Examiner notes that “it would have been obvious... to provide the splash shield of Marogil with the flexible sheet taught by Smith.” As mentioned above with respect to Claim 31, the Smith shield is the splash shield to be configured on a fluid deliver device, not another splash shield. Persons skilled in the art would not place one splash shield over another splash shield. For at least the same reasons discussed above for Claim 31, Smith does not teach either a flexible sheet being configured to fit over a conical splash shield or a flexible sheet sized to cover a wound area and a basin. Marogil, which teaches a spray nozzle and guard, does not rectify these failures.

For at least the forgoing reasons, Applicant submits that the combination of Marogil and Smith does not render Claim 99 obvious. Therefore, Applicant requests that the Examiner withdraw the rejection of Claim 99 and pass Claim 99 to allowance.

Dependent Claims 32, 34-48, 50, 100-102 Depend from Independent Claims 31, 49, or 99.

Applicant submits that Claims 32, 34-48, 50, and 100-102 also define over any cited reference, not only because they depend from one of Claims 31, 49, or 99, but also on their own merit.

New Claims 124 and 125 Are in Condition For Examination On Its Merits

By way of the present Amendment, Applicant has added new Claims 124 and 125 which are fully supported by the Specification as originally filed. *See, e.g.*, Paragraph [0224]. Thus, no new matter has been introduced. Additionally, Applicant submits that new Claims 124 and 125

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define over the cited references, not only because it depends from Claims 31 and 99 respectively, but also on their own merit.

SUMMARY

The undersigned has made a good faith effort to respond to all of the rejections and objections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: June 12, 2009

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